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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,574	09/14/2001	Thomas D. Lyster	US010599	7222

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/954,574	LYSTER ET AL.	
	Examiner	Art Unit	
	George R Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13,15-18 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-13, 15-18, 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by Olson et al (6125298). Olson uses the same electrodes on children and adults (the claimed "universal electrode" shown in figures 3-5 and 8). In addition, Olson shows in figure 8 that the universal electrode is removably coupled to the energy modifier or defibrillator system component, 304, to provide the different electrical waveforms.

Claims 1, 5, 16, 18, and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Morgan et al (6134468). Morgan states in column 4, line 45 that the electrodes used on children are the electrodes ordinarily used on adults. In addition, Morgan provides a presence detect signal in the energy reduction unit that will indicate and set the particular mode of the device to deliver adult or pediatric energy (the claimed "setting an adult/pediatric mode indicator" for claims 24 and 25) and teaches in Figures 6A and 6B the setting of the switches to provide no attenuation for an adult or attenuation of the energy for a child (for claims 24-26).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 7, 8, 9, 11, 12, 13, 17, and 18 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Olson et al. Olson discloses the increasing energy level shocks in column 9.

In the alternative, Olson discloses the claimed invention except for the particulars energies of the first and second waveforms, and the additional waveform energies of the second waveform (claims 1, 5, 8, 9, 11-13, 17, and 18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pediatric and adult defibrillation method as taught by Olson, with the particulars energies of the first and second waveforms, and the additional waveform energies of the second waveform since it was known in the art that pediatric and adult defibrillation methods use the particulars energies of the first and second waveforms, and the additional waveform energies of the second waveform to provide an effective waveform for defibrillation of adults and children.

Claim 7 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morgan et al. Morgan states that the defibrillator is an automatic defibrillator and will inherently determine whether defibrillation was successful in order to deliver additional shocks if necessary.

In the alternative, Morgan discloses the claimed invention except for the determination of whether defibrillation was successful. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the automatic defibrillator as taught by Morgan, with a determination of whether defibrillation was successful since it was known in the art that defibrillators determine whether defibrillation was successful in order to deliver additional shocks to stop fibrillation.

Claims 8, 9, 11, 12, 13, 17, and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. Morgan states that the defibrillator is an automatic defibrillator and will inherently determine whether defibrillation was successful in order to deliver additional shocks if necessary.

Morgan et al discloses the claimed invention except for the determination of whether defibrillation was successful (claims 8, 9, and 11), the particulars energies of the first and second waveforms, and the additional/incremental waveform energies of the second waveform (claims 8, 9, 11-13, and 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pediatric and adult defibrillation method as taught by Morgan, with a determination of whether defibrillation was successful, the particulars energies of the first and second waveforms, and the additional waveform energies of the second waveform since it was known in the art that pediatric and adult defibrillation methods use a determination

of whether defibrillation was successful in order to deliver additional shocks to stop fibrillation and since it was known that defibrillators use the particulars energies of the first and second waveforms, and the additional waveform energies of the second waveform to provide an effective waveform for defibrillation of adults and children.

Claims 3, 4, 10, and 15 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Olson et al. Olson uses the same electrodes on children and adults (the claimed "universal electrode"), shown in figures 3-5 and 8, and incorporates by reference three patents, 5697955, 5579919, 5402884, that show the conductive portion 56 with a hole/opening in it being a foil. In addition, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

In the alternative, Olson discloses the claimed invention except for the conductive portion, 56, being a foil. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode with conductive portion as taught by Olson, with the conductive portion being a foil since it was known in the art that defibrillation electrodes with conductive portions make the conductive portion out of a foil to provide an inexpensive, light, conductive portion that can easily distribute the defibrillation energy.

Claims 3, 4, 10, and 15 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morgan et al. It has been held that to be

entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

In the alternative, Morgan discloses the claimed invention except for the conductive portion of the electrode being a foil with an opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode with conductive portion as taught by Morgan, with the conductive portion being a foil with an opening since it was known in the art that defibrillation electrodes with conductive portions make the conductive portion out of a foil with an opening to provide an inexpensive, light, conductive portion that can easily distribute the defibrillation energy.

Response to Arguments

Applicant's arguments filed 7/6/04 have been fully considered but they are not persuasive. The argument that Olson (6125298) does not provide a universal electrode set is not persuasive. Olson states through columns 2-8, and incorporates by reference three patents in column 8, that the electrodes are ordinary adult electrodes 50A and 50B that deliver up to 300J to the patient. Olson states in columns 8 and 9 that there are "pediatric defibrillation sets", but states that the electrodes are the same electrodes 50A and 50B and that the electrodes can be used on a child. Therefore the electrodes are the claimed "universal electrode suitable for use upon both adults and children". It is noted that the claims only limit the "electrodes". In addition, Olson states in column 9 for figure 9 that the electrodes are all 50A and 50B and only the shunt resistance is different. Olson references a different embodiment disclosed in figure 10 for pediatric electrodes that can be a different size. In addition, Olson meets the claimed

limitation of "delivering" two different waveforms "characterized by an energy level appropriate for an adult" or "appropriate for a child" depending on whether the patient is an adult or child by either delivering the normal waveform characterized by a normal energy level to the electrodes or delivering a second waveform characterized by a reduced energy level to the electrodes through a reducing network for pediatric patients. Therefore, for figures 8 and 9, Olson determines whether the patient is an adult or child, either couples the universal electrodes, 50A and 50B, directly to the defibrillator or through the removable shunt resistor (for figure 8) or couples the appropriate set of electrodes with shunt (for figure 9) and delivers a waveform characterized by an energy level appropriate for an adult or child depending on the determination.

The argument that Morgan does not teach a "universal electrode" is not persuasive. Morgan teaches that the electrodes are used on both children and adults and therefore meet the broad claim limitation of a "universal electrode suitable for use upon both adults and children". Although Morgan states that pediatric electrodes "may be" used, this is just an alternate embodiment and does not negate his teaching of his universal electrode being used on both adults and children. In addition, his universal electrode is more in line with his goal of providing a system and method that does not complicate the defibrillation process by adding extra steps to the defibrillation procedure, such as by including different electrodes for a child or adult.

The statements that Morgan or Olson use an energy reduction unit or ID chip makes no difference since the claims are open ended "comprising" claims and the references meet the claimed limitation of delivering a waveform characterized by an energy level appropriate for a child or adult.

The argument that Olson uses a pediatric electrode set and not a universal electrode set suitable for both adults and children may be correct, but the claims are not directed to the electrode "sets" but only to the electrodes. Therefore, Olson meets the claim limitation of an electrode suitable for both adults and children. The arguments that no determination of whether the patient is an adult or child is done is not persuasive since a determination is done to know whether to connect a particular pediatric or adult electrode set (for figure 9) or to connect the energy modifier for a pediatric patient (for figure 8).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762
8/25/4

GRE
August 25, 2004